

1 NOAH T. KATZEN
2 Trial Attorney
3 Consumer Protection Branch
4 U.S. Department of Justice
5 P.O. Box 386
6 Washington, DC 20044-0386
7 (202) 305-2428
8 (202) 514-8742 (fax)
9 Noah.T.Katzen@usdoj.gov
10

11 UNITED STATES DISTRICT COURT
12 FOR THE EASTERN DISTRICT OF WASHINGTON
13

14 STATE OF WASHINGTON, *et al.*,

No. 1:23-cv-03026

15 Plaintiffs,

16 v.

DECLARATION OF NOAH T.
KATZEN

17 U.S. FOOD AND DRUG
ADMINISTRATION, *et al.*,

18 Defendants.
19

20 Pursuant to 28 U.S.C. § 1746, I, Noah T. Katzen, hereby declare:

21 1. I am an attorney in the U.S. Department of Justice, Civil Division,
22 Consumer Protection Branch. I am assigned to represent Defendants in the above-
23 captioned case. The statements made herein are based on my personal knowledge,
24 and on information made available to me in the course of my duties and
25 responsibilities as Government counsel in this case.
26

7. Attached hereto as **Exhibit 5** is a true and correct copy of Joint Summary Review (Jan. 3, 2023), included in the administrative record in this case at Bates Numbers 2023 SUPP 001112–001150.

8. Attached hereto as **Exhibit 6** is a true and correct copy of Letter from U.S. Food & Drug Admin. to Danco Laboratories, LLC re: Supplement Approval NDA 020687/S-025 (Jan. 3, 2023), included in the administrative record in this case at Bates Numbers 2023 SUPP 001448–001460.

9. Attached hereto as **Exhibit 7** is a true and correct copy of Letter from U.S. Food & Drug Admin. to GenBioPro, Inc. re: Supplemental Approval ANDA 091178-S004 (Jan. 3, 2023), included in the administrative record in this case at Bates Numbers 2023 SUPP 001461–001465.

10. Attached hereto as **Exhibit 8** is a true and correct copy of Jenna Jerman, et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Inst. (2016), included in the administrative record in this case at Bates Numbers 2021 REMS 001198-001226.

11. Attached hereto as **Exhibit 9** is a true and correct copy of ANSIRH, The Turnaway Study, which I downloaded from <https://www.ansirh.org/research/ongoing/turnaway-study> and captured at <https://perma.cc/257Q-LV5R> on February 2, 2024. This exhibit also includes the

1 annotated bibliography linked to on the cited page, which I downloaded from
2 [https://www.ansirh.org/sites/default/files/2022-](https://www.ansirh.org/sites/default/files/2022-12/turnawaystudyannotatedbibliography122122.pdf)
3 [12/turnawaystudyannotatedbibliography122122.pdf](https://www.ansirh.org/sites/default/files/2022-12/turnawaystudyannotatedbibliography122122.pdf) and captured at
4 <https://perma.cc/5TNG-GQKA> on February 2, 2024.
5

6 12. Attached hereto as **Exhibit 10** is a true and correct copy of Letter
7
8 from Advancing New Standards in Reproductive Health (ANSIRH) et al, to
9 Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs, Robert M.
10 Califf, M.d., Deputy Commissioner for Medical Products and Tobacco, and Janet
11 Woodcock, M.D., Director of the Center for Drug Evaluation and Research (Feb.
12 4, 2016), included in the administrative record in this case at Bates Numbers FDA
13 1254-1262.
14
15

16 I swear under penalty of perjury that the foregoing is true and correct.
17 Executed on February 2, 2024.
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19

20 /s/ Noah T. Katzen
21 NOAH T. KATZEN
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DECLARATION OF NOAH T. KATZEN